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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,859	12/17/2004	Kazuhiko Inoue	18493	5819
23389 7590 12/03/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER LISTVOYB, GREGORY	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 12/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,859

Applicant(s)

INOUE ET AL.

Examiner

Gregory Listvoyb

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44,47-71,74 and 77-130 is/are pending in the application.
- 4a) Of the above claim(s) 77-130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,44,47-71 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 77-130 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected resin composition and molded body and methods of producing biodegradable resins, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/24/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-44, 47-48, 51-53, 55-57, 59-61 rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (US patent 6018033), herein Chen.

Regarding Claims 43-44, 47-48, 53, 57, 60, 61, Chen discloses a modified Saccaride, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples III-1 and III-2 and Column 7, line 35).

Regarding Claim 52, a biodegradable resin can contain linear and branched structure (column 5, line 25).

Regarding Claims 51, 55 and 59, Chen discloses cross-linked density in terms of Swelling Ratio. This ratio changes within a broad range of 5-90%. According to Flory, cross-link frequency can be calculated from the above parameter (more crosslink frequency corresponds with less swelling ratio). In examiner's opinion, Chen's composition internally possesses cross-linked density to meet the limitations of the above Claims.

Claims 43, 49 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Onwumere et al (US patent 5491210), herein Onwumere.

Onwumere discloses a modified polycaprolactone (comprising a modified body of lactic acid) biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 4, line 30).

Claims 43-44 rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (US patent 6207762), herein Kobayashi.

Kobayashi a discloses a biodegradable thermally reversible (at 100-250C, Claim 16) crosslinked polyester-based composition (Column 3, line 60) with carboxyl-alkenoxy bond (Claim 4).

Claims 43-44 rejected under 35 U.S.C. 102(b) as being anticipated by Takao et al (JP publication 11-035675), herein Takao.

Takao discloses a thermo-reversible cross-linked composition, comprises a biodegradable polyester and contains alkenyl hydroxyl-carbonyl link. The above composition cleaves at 130-160C (Abstract, line 0010 and 0018 and Formula 1).

Claims 43-44 rejected under 35 U.S.C. 102(b) as being anticipated by Chino et al (US patent 6746562 and JP2002-2060422), herein Chino.

Chino discloses a thermo-reversible, crosslinkable elastomer, having stable cross-linked structure at room temperature and plasticity and moldability at mold temperature. (Abstract). The cross-linking can be achieved with different methods, including Diels-Alder (reaction of maleic anhydride with diene rubber, Column 8, line 55). Therefore, Chino's composition inherently meets the limitation of cleaved temperature over 120C.

Some of Chino's materials, such as aliphatic polyesters are biodegradable
(Column 5, line 50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 49, 54 and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable
over Chen in combination with Helmus et al (US publication 2004/0093080 and WO
0154745), herein Helmus

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols)
and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is
covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above
120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A
functional group can be dienyl, carboxyl, hydroxyl and others (Examples III-1 and III-2
and Column 7, line 35).

Chen does not disclose a biodegradable resin based on polylactic acid.

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068).

It would be obvious to a person with ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material is most commonly used and economical biodegradable material.

Claims 43, 50 and 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Chino.

Regarding claims 50 and 69, Chino teaches a resin, based on succinic acid and succinic anhydride (Column 27, line 30), but not specifically discloses polybutylene succinate (PBS). PBS is well known as a most commonly used biodegradable plastic with excellent mechanical properties, similar to PET.

It would be obvious to a person with ordinary skills in the art to use a modified PBS acid derivative in Chino's composition, since PBS is readily commercially available biodegradable plastic with excellent mechanical properties.

Claims 43, 47, 48, 62, 66-68 and 70-74 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in combination with Kozo (JP publication 2000-28105) herein Kozo.

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C.

Chen does not teach ion-crosslinking compositions.

Kozo discloses polysaccharide-based ion-crosslinking film and its production (Abstract). Kozo teaches that in order to create ion-crosslinking polysaccharide composition divalent ions added to the composition.

It would be obvious to a person with ordinary skills in the art to add divalent metal ions to Chen's composition to create both covalent and ionic reversible crosslinked structure. It would diversify a number of applications for Kozo's composition. For instance, Kozo's composition can be used in drug delivery systems and other *in-vivo* applications.

Response to Arguments

Applicant's arguments filed on 9/24/07 have been fully considered but they are not persuasive.

Applicant states that "the claims have been amended herein to more particularly point out and distinctly claim the subject matter regarded as inventive to reflect that the TRSL structures possess a Diels Alder type functional group selected from the group consisting of an alkenyl group and a group having a conjugated double bond".

However, the references cited above still meet the amended claims. In particular, as evidences by Merck Index (Diels-Alder reaction, ONR-23, Merck and Co, 1996), Diels-Alder reaction always involve alkenyl ($\text{CH}_2=\text{CH}_2\text{-R}$) group.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Listvoyb whose telephone number is (571) 272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory Listvoyb
Examiner
Art Unit 1796

GL


RABON SERGENT
PRIMARY EXAMINER